REMARKS

Claims 1-7, 10, 14, 16-18, and 32-67 are pending. Claims 1-5, 7, 10, 14, 16-18, 32-34, and 36-47 were withdrawn from consideration. Claims 48-67 were objected to as directed to non-elected subject matter. Claims 6, 35, and 48-67 were rejected under 35 U.S.C. § 112, first paragraph, and claims 61-64 were rejected under the judicially created doctrine of obviousness-type double patenting. Applicants address each of these rejections as follows.

Claim amendments

Claims 48-54 have been canceled. Applicants have amended the dependency of claims 55, 58, 61, and 65. No new matter has been added by this amendment.

Restriction Requirement

The Office withdrew claims 36-47 from consideration as being directed to an invention that is independent or distinct from the previously elected invention. Claims 36-47 therefore have been canceled.

Rejection under 35 § U.S.C. 112, first paragraph

Claims 6, 35, and 48-67 were rejected under 35 § U.S.C. 112, first paragraph on the basis that the disclosure in Applicants' specification (1) is not commensurate in scope

with the claimed invention and (2) fails to provide a written description of the claimed invention. Claims 48-54 have been canceled and this rejection of these claims, therefore, is moot. For the following reasons, these rejections of claims 6 and 35, and their dependent claims, may be withdrawn.

Enablement

Claims 6, 35, and 48-67 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and use the invention. In particular, the Office Action states (page 5):

> [T]he specification does not provide sufficient guidance for one skilled in the art to use nucleic acid molecules encoding a protein or polypeptide comprising the amino acid sequence of SEQ ID NO:5. Applicant has disclosed the elected nucleic acid sequence of SEQ ID NO:4 which encodes the amino acid sequence of SEQ ID NO:5, and has assigned the structure on the basis of homology to the proteinase of Hepatitis C virus, but Applicant has not demonstrated a proteinase function for SEQ ID NO:5.
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> * * *
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> Because no functions has been demonstrated for the polypeptide of SEQ ID NO:5, the claimed invention is not enabled by the specification in the absence of further guidance or example.

The Office also cited Doerks et al. (Trends in Genetics 14:248-250, 1998; "Doerks") in support of the assertion that "the degree of shared homology within a functional region

does not always predict a conservation of the functional mechanism of that region." Applicants disagree.

As is noted above, independent claims 6 and 35 are directed to an isolated RNA and DNA molecule, respectively, encoding a polypeptide including the amino acid sequence of SEQ ID NO:5. Applicants submit that one skilled in the art, given Applicants' disclosure of SEQ ID NO:5, would be able to make and use nucleic acid sequences encoding an amino acid sequence that includes the sequence of SEQ ID NO:5, without undue experimentation. In fact, the skilled artisan simply would have to determine if an isolated nucleic acid molecule encodes a sequence including that set forth in SEQ ID NO:5. This level of skill clearly is standard in the art. Thus, on this basis alone, Applicants submit that claims 6 and 35 are enabled by Applicants' specification.

Turning to Doerks, Applicants submit that this reference does not teach that homology is not useful in predicting function. In fact, Doerks uses homology to classify database proteins into families with similar predicted functions (p. 248, second column), and encourages others skilled in the art to undertake careful functional annotation of homologous database sequences (page 250, last two paragraphs). Thus, Doerks fails to suggest that homology is not indicative of protein function, but rather teaches that homology has to be carefully reviewed by one skilled in the art to predict the likely function of a protein. As is taught by Doerks, one skilled in the art would be able to analyze homologous proteins to identify ones that likely have similar functions.

Furthermore, neither Doerks nor the Office provide any evidence or reason to doubt the existence of viral proteinase genes. In fact, many plant viral genomes, if not all, possess genes that encode such proteinases, see for example, Maiti et al. (*Proc. Natl. Acad. Sci.* 90: 6100-6114, 1993; "Maiti" (copy enclosed)) and Vardi et al. (*Proc. Natl. Acad. Sci.* 90: 7513-7517, 1993; "Vardi" (copy enclosed)). Given the organization of plant viral genomes, the existence of proteinase genes in plant viruses, and the fact that Applicants identified a domain indicative of such proteinases, there is little reason to doubt that one skilled in the art would question the proteinase function Applicants' have assigned to the protein of SEQ ID NO:5.

The Office further challenges Applicants' claims on the ground that their specification has not demonstrated that "expression of a nucleic acid encoding a protein or polypeptide comprising amino acid sequence of SEQ ID NO:5 will confer any type or amount of viral resistance to a transgenic plant." The Office, in essence, argues that because Applicants' examples are prophetic, there can be no guarantee that the examples would actually work. Applicants disagree.

Applicants clearly describe in their specification, for example, at pages 13 (line 7) – 16 (line 1) how to generate and identify plants having viral resistance. Applicants' use of prophetic examples, however, does not automatically make its specification non-enabling. The burden is on the one challenging the specification to show that the prophetic examples together with other parts of the specification are not enabling. See,

for example, *Atlas Powder Co. v. E.I. DuPont De Nemours*, 750 F.2d 1569, 1577 (Fed. Cir. 1984). The Office has not met this standard. The ability of a proteinase gene nucleic acid sequence to confer viral resistance is readily established using any of a variety of methods, including a straightforward, one-step screening technique. The specification makes clear that broad-spectrum viral resistance is readily obtained by expressing proteinase transgenes at sufficiently high levels to initiate a plant defense response. Accordingly, a skilled worker need only prepare a plant or plant component expressing a gene encoding a grapevine leafroll virus proteinase, and then evaluate the plant's ability to combat a viral pathogen. All such methods were standard in the art when the application was filed, and the Office has provided no evidence negating these facts. Indeed, such a single-step screening approach cannot constitute undue trial and error experimentation.

Moreover, the Maiti and Vardi references clearly support the notion that proteinase genes, such as the gene identified by Applicants, when expressed in a plant, confer viral disease resistance. Indeed, proteinase genes, like other virus-derived genes, are useful for the production of plants resistant to viral pathogens. The Office's prediction that expression of Applicants' proteinase gene would not confer viral disease resistance is unsupported by the cited art.

For all of the above reasons, the enablement rejection should be withdrawn.

Written Description

Claims 6 and 35 are directed to an isolated RNA or DNA molecule, respectively, encoding a protein or polypeptide including the amino acid sequence of SEQ ID NO:5.

Applicants' specification clearly describes the presently claimed sequences and, accordingly, satisfies the written description requirement. This is because these claims are drawn to the genus of DNAs or RNAs that encode amino acid sequence SEQ ID NO:5. Although Applicants' have described only one species falling within this genus, SEQ ID NO:4, a person of ordinary skill in the art would readily envision all the DNAs or RNAs degenerate to this sequence by using the genetic code. Accordingly, one of skill in the art would conclude that Applicants were in possession of the claimed genus based on Applicants' specification and the general knowledge known in the art regarding the genetic code. Applicants submit, with regard to claims 6 and 35, that the specification clearly satisfies the written description requirement.

Rejections under the judicially created doctrine of obviousness-type double patenting

Claims 61-64 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 30 of U.S. Patent No. 5,907,085 ("the '085 patent"). Applicants address this rejection as follows.

Claim 1 of the '085 patent is directed to a transgenic Vitis scion cultivar or rootstock cultivar including a DNA molecule encoding a protein or polypeptide of a

grapevine leafroll virus, and claim 30 of this patent, which depends from claim 1, requires that the DNA molecule includes the nucleic acid sequence of SEQ ID NO:24. In contrast, present claims 61-64 employ an isolated DNA molecule that encodes a protein or polypeptide including the amino acid sequence of SEQ ID NO:5. Such nucleic acid molecules are nowhere taught or suggested by the '085 patent.

While claims 61-64 may be directed to a species encompassed by claim 1 of the '085 patent, this alone cannot be the basis for an obviousness-type double patenting rejection. The Federal Circuit has held that "domination," e.g., where a generic claim in one patent reads on a narrower or more specific claim in another patent, by itself does not give rise to double patenting. *In re Kaplan*, 789 F.2d 1574, 1577, 229 U.S.P.Q. 678 (Fed. Cir. 1986). Instead, the proper analysis for obviousness-type double patenting involves determining whether any claim in the application defines merely an obvious variation of an invention disclosed and claimed in a patent. *In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619 (Fed. Cir. 1970).

As noted above, the isolated nucleic acid molecules claimed in the present application encode SEQ ID NO:5. These nucleic acid molecules are not taught or suggested by the '085 patent. Clearly, in the absence of such a teaching or suggestion, the '085 patent cannot render the presently claimed invention obvious. Applicants submit that claims 61-64 are patentably distinct over claims 1 and 30 of the '085 patent, and, therefore, are free of the rejection under the judicially created doctrine of obviousness-

type double patenting.

CONCLUSION

Applicants submit that the claims are in condition for allowance and this action hereby is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including November 20, 2003, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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